July 3, 2020

Medtronic, Inc.
Eric Kalmes
Sr. Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K200795
Trade/Device Name: LINQ II Insertable Cardiac Monitor, LINQ Mobile Manager, Device Command Library, Instrument Command Library, LINQ Tool Kit
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MXD, DSI
Dated: June 19, 2020
Received: June 22, 2020

Dear Eric Kalmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Acting Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200795

Device Name
LINQ II Insertable Cardiac Monitor

Indications for Use *(Describe)*
The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: March 13, 2019

Submitter: Medtronic, Inc.
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8200 Coral Sea Street N.E.
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Establishment Registration Number: 2182208

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General Information

Trade Name: LINQ™ II Insertable Cardiac Monitor

Common Name: Insertable Cardiac Monitor

Regulation Number: CFR 870.1025

Product Code: MXD

Classification: Class II

Classification Panel: Cardiovascular

Special Controls: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

Predicate Device: Primary Predicate Reveal LINQ Insertable Cardiac Monitor (Model LNQ11) K162855 and additional supporting predicate Reveal XT Model (Model 9529) K071641

Device Description

The LINQ II Insertable Cardiac Monitor (ICM) Model LNQ22 is a programmable device that continuously monitors a patient's ECG and other physiological parameters. The device records cardiac information in response to automatically detected arrhythmias and patient-initiated activation or markings. The device is designed to automatically record the occurrence of an episode of arrhythmia in a patient. Note: Arrhythmias are classified as tachyarrhythmia, bradyarrhythmia, pause, atrial tachyarrhythmia, or atrial fibrillation. Patients may also manually record symptoms. In order to manually record symptoms, the patient will also need either the MyCareLink Heart App (patient app on mobile device) or the Patient Assistant Model PA97000. The patient can use the MyCareLink Heart App or the Patient Assistant to manually record his or her cardiac rhythm while experiencing or immediately after a symptomatic event. LINQ II ICM and this submission includes the following accessories: LINQ Tool Kit Model LNQ22TK, Reveal LINQ™ Mobile Manager Model MSW002, Device Command Library Model 2692, and Instrument Command Library Model 2691.

Accessories Subject to this Submission

- The LINQ Tool Kit Model LNQ22TK includes two implant tools: The Incision Tool is used to make a small incision through the patient's skin; and the Insertion Tool is used to insert the device through the incision and into the patient's body at the desired location.
- The Reveal LINQ™ Mobile Manager (LMM) Model MSW002 is the programmer designed as a mobile app that communicates with the Reveal LINQ and LINQ II ICM devices via the existing model 24967 telemetry head.
- The 2692 Device Command Library (DCL) software is a component of the Data Transformation Services subsystem of the CareLink Network. This software is responsible for understanding command status, implant device state within CareLink, and the initiation of commands for the implanted device.
- The 2691 Instrument Command Library (ICL) software is the logic and data files required for remote programming.

Indications for Use

Aside from the name of the device, there are no changes as compared to the Reveal LINQ ICM Indications for Use as a result of this submission. The Indications for Use are provided below:

The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Technological Characteristics

The LINQ II ICM consists of a hybrid substrate that is made of sapphire. The sapphire provides part of the implantable hermetic enclosure, integrates the feedthroughs directly into the substrate,

and provides a substrate for component attachment/interconnect. The antenna and sense electrodes are titanium foil laser bonded to the outside of the sapphire substrate and connected directly to the embedded feedthroughs. The sense electrodes will be coated with sputtered titanium nitride. The sapphire will be laser bonded to the titanium battery cover, which provides the complete hermetic enclosure. The battery is Lithium anode, silver vanadium oxide/carbon monofluoride cathode with a capacity of 167 mAh.

The LINQ II ICM will continue to use the same technology. It is designed to automatically record the occurrence of an arrhythmia in a patient, continuously sense the patient's subcutaneous ECG, and analyze the timing of ventricular events to detect possible episodes of arrhythmia. The LINQ II ICM has a small form factor, and uses Sapphire, Titanium, Parylene, and Titanium Nitride coating on the sensing electrodes as body contacting materials.

When compared to the predicate device, the existing Reveal LINQ ICM (most recently cleared by FDA under K162855), the LINQ II ICM has the same:

- Indications for use
- Operating principle
- Device functionality
- Biological safety

When compared to the predicate device, the existing Reveal LINQ ICM (most recently cleared by FDA under K162855), the LINQ II differs as follows:

- 4.5-year longevity
- Bluetooth Low Energy (BLE) technology to enable communication with mobile devices via a mobile application.
- The LINQ II ICM includes minor changes to enhance the arrhythmia detection algorithms and diagnostics which include pause detection and PVC detector.
- The insertion tool is being updated to accommodate the LINQ II device form factor.
- CareLink Network enhancements to support the LINQ II device remote follow-up. This includes updates to the Instrument Command Library and Device Command Library.
- Reveal LINQ Mobile Manger updates to support LINQ II ICM.

Substantial Equivalence

Technological differences between the subject and predicate devices have been evaluated through bench and animal testing. The LINQ II ICM is substantially equivalent to the predicate device, the existing Reveal LINQ ICM (cleared by FDA under K162855) based on comparisons of device functionality, technological characteristics, and indications for use.

Summary of Testing

Firmware testing, design verification, system verification, and system design validation testing were performed to demonstrate that the subject device, the LINQ II ICM, met established

performance criteria to support equivalency to the referenced predicate device, the existing Reveal LINQ ICM (cleared by FDA under K162855).

- **Firmware design verification:** This testing was made up of two parts: verification of the individual design artifacts (firmware units) associated with the development and release of the firmware; and verification of the finished firmware product (implemented design) to confirm that it meets the associated input requirements.
- **Firmware regression testing:** This testing of unchanged firmware was performed to ensure that no unintended side effects were introduced.
- **Verification testing:**
  - Mechanical
  - Electrical
  - Electromagnetic compatibility (EMC) and electrical safety
  - Sterilization
  - Biocompatibility
  - MRI Compatibility
  - Sensing and detection performance validation
  - Packaging testing
  - Human Factors
  - Security
- **System testing:** This testing was performed on the subject device (LINQ II) and its accessories which included system verification testing and system validation testing. System design verification ensured that the proposed modifications did not impact the existing system level design inputs. System design validation confirmed through a combination of test and analysis that the stakeholder needs and intended use continued to be met by the subject device.

The following standards and guidance documents were used for development and testing of the LINQ II device:

Standard Number	Standard Organization	Recognition Number	Standard Title
14971:2012	ISO	5-40	Medical Devices - Application of Risk Management to Medical Devices
62304:2006	IEC EN	13-32	Medical device software - Software life-cycle processes
EC57:1998	AANSI/AAMI	3-118	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
62366: 2007/(R)2013	AAMI/ANSI/ IEC	5-114	Medical devices – Application of usability engineering to medical devices
15223-1:2012	ISO	5-117	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements
10993-1: 2009/(R)2013	AAMI/ANSI/ ISO	2-220	Biological evaluation of medical devices. Evaluation and testing
11135-1:2014	EN ISO	14-452	Medical Devices – validation and routine control of ethylene oxide sterilization
60601-1: 2005 (2nd Edition) and 2006 (3rd Edition)	EN	19-1	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
11607-1:2009	EN ISO	14-454	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
14117:2012	ISO	3-139	Active implantable medical devices -- Electromagnetic compatibility -- EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices.
14708-1:2000	ISO	3-156	Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
Guidance	FDA	Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm	
Guidance	FDA	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	

Guidance	FDA	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 14 June 2013 and revised edition of the pre-market guidance document issued on October 18, 2018

The following standards were used for development and testing of the Reveal LINQ™ Mobile Manager:

Standard Number	Standard Organization	Recognition Number	Standard Title
14708-1:2014	ISO	3-156	Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
14971:2007	ISO	5-40	Medical devices – Application of risk management to medical devices
15223-1:2016	ISO	5-117	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
62304:2006/AMD1:2015	IEC	13-79	Medical device software – Software life cycle processes
62366-1	IEC	5-114	Medical devices – Part 1: Application of usability engineering to medical devices

The following standards were used for development and testing of the Device Command Library Model 2692:

Standard Number	Standard Organization	Recognition Number	Standard Title
EN ISO 14971: 2012	ISO	5-40	Medical devices – Application of risk management to medical devices
EN 60601-1: 2006/ A1:2013	EN	19-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 62304:2006/ A1:2015	IEC EN	13-32	Medical device software. Software life-cycle processes

The following standards were used for development and testing of the Instrument Command Library, Model 2691:

Standard Number	Standard Organization	Recognition Number	Standard Title
EN ISO 14971:2012	ISO	5-40	Medical devices - Application of risk management to medical devices
EN 60601-1: 2006/AC:2010	EN	19-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 62304:2006/ A1:2015	IEC	13-32	Medical device software. Software life-cycle processes

Conclusion

The results of the above testing met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the LINQ II Insertable Cardiac Monitor Model LNQ22 and its accessories, which include: LINQ Tool Kit Model LNQ22TK, Reveal LINQ™ Mobile Manager Model MSW002, Device Command Library Model 2692, and Instrument Command Library Model 2691, described in this submission result in a device that is substantially equivalent to the predicate.